

UNITED STATES OF AMERICA  
BEFORE THE FOOD AND DRUG ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES

\_\_\_\_\_)  
In the Matter of: )  
)  
)  
Enrofloxacin for Poultry: Withdrawal )  
of Approval of Bayer Corporation's )  
New Animal Drug Application )  
(NADA) 140-828 (Baytril) )  
\_\_\_\_\_)

FDA DOCKET: 00N-1571  
DATE: February 2003

**ORDER**

By Motion filed February 25, 2003 the Center for Veterinary Medicine ("CVM") seeks to supplement its document submission under 21 C.F.R. §12.85 and enter Exhibit G-1799 ("Short and long term mortality associated with foodborne bacterial gastrointestinal infections: registry based study" by Morten Helms, Pernille Vastrup, Peter Gerner-Smidt, and Kare Molbak, published on February 15, 2003 in the British Medical Journal, and the accompanying published commentary) into the evidentiary record of this hearing. On February 28, 2003, Respondent Bayer Corporation filed its response in opposition.

Respondent asserts that Exhibit G-1799 article is not relevant to the issues in this proceeding and "...has generated substantive critical comments from the medical community." Respondent concludes, in the alternative, that should CVM's motion be granted, Exhibit B-1922 (the critical comments) should also be added to the evidentiary record.

Exhibit G-1799: is relevant and material to the issue of this hearing. It is a recent peer-reviewed publication of some data already referred to on this Record. CVM's Motion to Supplement its document submission under 21 C.F.R. §12.85 and to move Exhibit G-1799 into the evidentiary record of this hearing is therefore GRANTED.

Respondent's alternative request to add Exhibit B-1922 will be treated as a motion to that effect, and pursuant to the authority contained in 21 C. F. R. §12.99(b), the time for replies thereto is hereby shortened so as to require that any reply be filed on or before March 7, 2003.

DATED this the 3<sup>rd</sup> day of March, 2003.

s/s Daniel J. Davidson  
Daniel J. Davidson  
Administrative Law Judge

00N-1571

OR 30